

REMARKS

Claims 1-45 were pending in this application. Claims 1, 31, 34 and 40 have been amended to clarify that the component is a supermolecular structure formed by a plurality of molecules. Claim 42 has been amended for appropriate spacing between a listing of numbers. These amendments are supported throughout the specification, and particularly at page 27, lines 32-34 of the application as filed, and add no new matter.

Restriction Requirement

The Examiner has required restriction of the claims under 35 U.S.C. §§ 121 and 372. More specifically, the Examiner has required restriction to one of the following groups:

Group I	Claim(s) 1-30, 41, 42 and 45, drawn to an assembly comprising a gas-filled microvesicle.
Group II	Claim(s) 31-34, drawn to a kit.
Group III	Claim(s) 35-40, drawn to a method for preparing an assembly.
Group IV	Claim(s) 43, drawn to a method for ultrasound diagnostic imaging.
Group V	Claim(s) 44, drawn to a method for therapeutic treatment.

The Examiner asserts that the inventions of Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because they allegedly lack the same or corresponding special technical features. Applicants respectfully traverse. The currently pending claims, relating to an assembly, a kit, a method for preparing an assembly, a method of ultrasonic imaging or a method of therapeutic treatment were properly deemed to comply with the PCT rules during the international phase and the instant restriction requirement appears to violate PCT Article 27(1): *no national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.* . See., *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 650 F. Supp. 218,231 USPQ 590 (E.D. Va 1986)

Further Applicants submit that contrary to the Examiner's assertion, all of the pending claims do share the same special technical features: all require an assembly comprising a gas-filled microvesicle bearing a first overall net charge and a component associated with said

microvesicle wherein said component is a supermolecular structure formed by the association of a plurality of molecules, which bears a second overall net charge opposite in sign to said first net charge, comprises a biocompatible surface active agent and has a diameter of 100 nm or lower.. The claimed compositions are not disclosed or suggested in the cited art.

While the Examiner alleges Unger (US 7,083,572, hereafter “Unger”) teaches targeted therapeutic delivery systems comprising gas or temperature activated gaseous precursor filled lipid microspheres comprising a therapeutic compound and a negatively charged lipid, this construct does not include the special technical features of the claims. In particular, Unger does not disclose a component to be associated with the microvesicle comprising a biocompatible surface agent. Indeed, Unger teaches only DNA or drug molecules. Moreover, as the instant amendment clarifies, the claims require that the component is a supermolecular structure formed by the association of a plurality of molecules (comprising surface active agent molecules). This feature is neither taught nor suggested by Unger. Thus the instant claims are novel and unobvious over the prior art, are in compliance with PCT Rule 13.1 and 13.2 and restriction is improper.

However, for the purposes of submitting a complete response, Applicants hereby elect Group I – Claims 1-30, 41, 42 and 45, drawn to an assembly comprising a gas-filled microvesicle, with traverse.

Species Election Requirement

The Examiner has required election of the following species:

i)	a <i>specific</i> chemical species corresponding to a constituent which imparts a first overall net charge to the microvesicle.
ii)	a <i>specific</i> chemical species corresponding to the component associated with the microvesicle that bears a second overall net charge that is opposite in sign to the first overall net charge.
iii)	a <i>specific</i> chemical species corresponding to the surface active agent.

Applicants respectfully traverse the species election. For the reasons explained in connection with the restriction requirement, the claimed species are believed to be in full compliance with the PCT rules and to share the same special technical features. Consequently Applicants submit that the species election is improper.

However, for the purposes of submitting a complete response, Applicants elect the following species with traverse:

- i) DSTAP (1,2-Distearoyl-3-trimethylammonium-propane chloride);
- ii) polyethyleneglycol modified phospholipid; in particular DSPE-PEG2000 (Distearoylphosphatidylethanolamine modified with PEG2000, sodium salt)
- iii) polyethyleneglycol modified phospholipid; in particular DSPE-PEG2000 (Distearoylphosphatidylethanolamine modified with PEG2000, sodium salt)

Applicants identify claims 1-15, 18-24, 27-30, 41, 42 and 45 from Group I as reading on the elected species.

Potential Rejoinder

If the restriction requirement is maintained despite Applicants traversal, Applicants request rejoinder of the dependent method claims at the appropriate time.

No fee is believed to be necessary in connection with the filing of this Amendment and Response to Restriction Requirement. However, if any additional fee is necessary, applicant hereby authorizes such fee to be charged to Deposit Account No. 50-2168.

Favorable action is respectfully requested.

Respectfully submitted,

Dated: May 18, 2010

/M. Caragh Noone/ .

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